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The Constitutionality of Restricting the Use of Prescriber-Identifiable Data in Pharmaceutical Detailing After *Citizens United v. FEC*

Bryson B. Morgan

Class of 2011

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ABSTRACT

Each year, the pharmaceutical industry spends billions of dollars dispatching sales representatives to meet with health care providers in order to promote their company's drug products. To assist these representatives to efficiently and effectively deliver their sales messages, pharmaceutical companies rely on data concerning individual physician prescribing habits. However, several states are considering, and a few states have enacted, legislation that restricts the ability of pharmaceutical companies to utilize such data for commercial purposes. Such legislation is a response to concerns over the rising costs of prescription drugs, the close relationship between the pharmaceutical industry and the medical profession, and concerns over the privacy of patient information. To proponents of regulation, the use of the data allows pharmaceutical companies to manipulate physicians into prescribing their products. To date, such legislation has withstood legal challenges from the industry, which claimed that such restrictions violate their First Amendment rights to free speech. However, it is likely only a matter of time before the question reaches the Supreme Court of the United States, and the Court's recent decision in *Citizens United v. FEC* suggests that such restrictions are likely to be held unconstitutional.

I. AN OVERVIEW OF THE PRACTICE OF PHARMACEUTICAL DETAILING

Pharmaceutical companies spend billions annually on "detailing": the promotion of prescription drugs through one-on-one visits to physicians and other health care professional by pharmaceutical representatives. There are estimated to be more than 90,000 pharmaceutical representatives in the United States, with roughly one representative for every 6 physicians,[1] and an estimated one sales representative for every two frequently-prescribing physicians.[2] The Congressional Budget Office estimates that pharmaceutical companies spent more than $12 billion on detailing in the United States in 2008.[3] This figure represents an increase from an estimated $11 billion spent in 2004 and an estimated $5.5 billion spent in 2000.[4] Estimates of the amount spent on detailing, however, vary widely. Because most estimates are based on figures self-reported from pharmaceutical companies to health information organizations ("HIOs"),[5] some estimate that the actual amount spent on detailing and other promotional activities could be almost 200% higher.[6] The return to pharmaceutical companies on their investment in detailing can be significant—an

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[1] L. Lewis Wall & Dounglas Brown, *The high cost of free lunch*, 110 OBSTETRICS & GYNECOLOGY 169 (2007).
[2] Michael Goldberg, Tiffany Mortellito, & Bob Davenport, *PE's annual sales and marketing employment survey: The big squeeze*, PHARM. EXEC. (Jan. 1, 204) available at http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=80921 .
[3] Congressional Budget Office, *Promotional Spending for Prescription Drugs*, 2 (2009) available at http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo_Brief.pdf.
[4] *Id.*
[5] *Id.* at n.5 (explaining that CBO's data set was constructed using information from SDI).
[6] Marc-Andre Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 1, available at http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001#pmed-0050001-b010 (estimating that the amount spent on detailing in 2004 was actually $20.4 billion, and not IMS's estimate of $7.3 billion.).

increase in one prescription per week per prescribing physician can result in millions of dollars of additional sales.[7]

At its core, detailing is providing physicians with information about a company's drug products and their approved uses. The practice, however, has evolved into more than simple sales pitches given in doctor's offices. The pharmaceutical industry utilizes gift-giving to facilitate brand recognition, friendship, and access, and has developed sophisticated data-driven physician marketing strategies designed to optimize the effectiveness of their sales force.

1. The role of friendship and pharmaceutical gifting in detailing.

Sales representatives are selected in part for their interpersonal skills and trained to cultivate personal relationships with physicians. Through the practice of "pharmaceutical gifting," physicians receive free meals, drug samples, pens, coffee mugs, magnets, notepads, and several other items from pharmaceutical companies. Sales representatives also identify widely-regarded physicians and invite them to give paid speeches to other physicians, or offer them positions as paid consultants, give them free trips, offer free physician-office management consulting,[8] or, in rare instances, they have even paid physicians to allow sales representatives to observe examinations of patients.[9]

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[7] The Prescription Project, Fact Sheet: Prescription Data Mining, available at http://www.communitycatalyst.org/doc_store/publications/prescription_data_mining.pdf.

[8] JEROME P. KASSIRER, M.D., ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (Oxford University Press 2005) at 13.

[9] *Id.* (citing Peterson, M., *Suit says company promoted drug in exam rooms*, N.Y. TIMES (May 15 2002) at C1).

These practices have become the subject of much attention and controversy. In response to criticisms of the interactions between sales representatives and physicians, in 2001 the American Medical Association ("AMA") issued guidelines prohibiting physicians from accepting personal gifts of "substantial value" or any gifts that do not benefit patients, and meals that are more than "modest."[10] In 2002, the Pharmaceutical Research and Manufacturers of America ("PhRMA") issued similar guidelines to its members.[11] Yet, there is no doubt that many physicians still receive substantial items of value from pharmaceutical sales representatives. For example, a recent survey of physicians revealed that 83% regularly accept free meals from pharmaceutical sales representatives.[12]

Importantly, the values of these gifts are often substantial. According to documents recently submitted to Congress as required by the 2010 health care reform bill,[13] in 2007 Pfizer sales representatives gave out 101 million prescription drug samples worth $2.7 billion, Merck & Co. representatives handed out 39 million samples worth $356 million, and Eli Lilly & Co. distributed 33 million samples worth $67 million.[14]

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[10] American Medical Association, *Opinion 8.061: Gifts to physicians from industry* (2001) available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml.
[11] PhRMA, *Code on Interactions with Healthcare Professionals* (2002), available at http://www.phrma.org/code_on_interactions_with_healthcare_professionals.
[12] Eric G. Campbell, Russell L. Gruen, James Mountford, Lawrence Miller, Paul D. Cleary, & David Blumenthal, *A national survey of physician-industry relationships*, 356 N. ENGL. J. MED. 1742 (2007).
[13] Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010).
[14] Jared A. Favole, *Drug Makers Provide View of Sampling Practices*, WALL ST. J. (June 5, 2010) available at http://online.wsj.com/article/SB10001424052748704764404575286423798063474.html.

Due to increased demands on physician's time, and criticism of pharmaceutical gifting, detailing has become a less effective marketing strategy. [15] Widespread criticism of the close relationships between physicians and sales representatives combined with an oversaturation of sales representatives has produced physicians who are less willing to meet with sales representatives. According to a recent survey, 23% of physicians now refuse to meet with pharmaceutical sales representatives and an increasing percentage of physicians—49.6%—prefer or require sales representatives to make appointments to see them.[16] Another survey indicates that from 2009 to 2010, the number of physicians who refused to meet with pharmaceutical representatives increased by 50%.[17]

2. The increasing importance of data in detailing.

The decline in physician willingness to meet with sales representatives has greatly increased the importance of data utilizing in the detailing process.[18] Sales representatives no longer have the luxury of spending several minutes with each of their assigned physicians each week, which allowed for representatives to adjust their message and approach mid-conversation.[19] Instead, sales representatives

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[15] Pankaj Kumar & Ron Brand, *Detailing Gets Personal*, PHARM. EXEC. (Apr. 1, 2003) available at http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=64071 (noting that a focus on large volumes of sales representatives and a high numbers of physician visits has led many physicians to become less receptive to sales representatives).
[16] SK&A, *Physician Access,* (2010), available at http://www.skainfo.com/health_care_market_reports/physician_access_pharma.pdf.
[17] Thomas Sullivan, *Pharmaceutical Reps Seen by Fewer Physicians*, POLICY & MED. (May 10, 2010) available at http://www.policymed.com/2010/05/pharmaceutical-reps-seen-by-fewer-physicians.html.
[18] A. Fugh-Berman, S. Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLOS MED 150 (2007), available at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040150#pmed-0040150-b026.
[19] Chris Nickum & Tim Kelly, *Missing the Mark(et)*, Pharm. Exec. (Sept. 1, 2005) available at http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=177968.

must be more selective in scheduling visits and be prepared to deliver a customized and successful message in a matter of a few minutes. To aid their sales forces in selecting which physicians to visit and what messages to deliver, pharmaceutical companies have sought the assistance of HIOs such as IMS Health Inc., SDI Health LLC (formerly Verispan), Wolters Kluwer Pharma Solutions Inc., and Source Healthcare Analytics Inc., which focus on gathering data about physicians and their prescribing trends.[20] Tracking the prescribing practices of individual physicians allows pharmaceutical companies to monitor the performance of their drug representatives and provide them with customized messages designed to convince the physicians they meet with to prescribe their drug products. The methods HIOs employ to gather prescription data, however, are part of the controversy.

During the course of filling prescriptions, pharmacies gather what is known as "prescriber-identifiable data" ("PI data"). PI data includes the date a prescription was filled, the name of the patient receiving the prescription, the Drug Enforcement Agency ("DEA") license number of the prescribing physician or similar physician identifier, and the name, dosage, and quantity of the prescribed drug product. PI data is sold to HIOs, who install software on pharmacy computers to convert those portions of the PI data that identify patients into "de-identified" codes before the data is transmitted from the pharmacy in order to comply with the

[20] For example, IMS Healthcare's 2009 Annual Report states that sales to pharmaceutical companies accounted for 85% of their revenue in 2009 and boasts that "[a]ll major pharmaceutical and biotechnology companies are our customers." *See* IMS Healthcare Inc., 2009 Annual Report, available at *http://www.imshealth.com/imshealth/Global/Content/Document/Annual%20Reports/IMSHEALTHINC10K.pdf*.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which only permits the release of the "de-identified" PI data.[21]

Having been scrubbed of patient-identifying data and transmitted to the HIO, the PI data is then matched with "prescriber-reference data," ("PR data") purchased from the American Medical Association ("AMA"), whose Physician Masterfile includes DEA license numbers matched to the physician's name, address, education credentials, and specialties.[22] Matching the PI data from pharmacies with the PR data in the Physician Masterfile allows HIOs to produce almost instantaneous and detailed reports and analysis of the prescribing trends of individual physicians. Additionally, many HIOs combine the PI and PR data with demographic and psychographic information (personality characteristics) to further predict the types of sales approaches suitable to particular physicians in a process called integrated segmentation.

This data is then sold to pharmaceutical companies, which use it to categorize physicians, to create customized sales messages for each category of physicians, and to track the performance of their sales representatives and effectiveness of their messaging. For example, physicians who prescribe the company's drug products frequently are often categorized as "high prescribers" or "loyal prescribers," and physicians who prescribe newly-released medications are identified as "early adopters." Physicians who appear to only prescribe the

[21] 45 C.F.R. § 164.502(d)(1) (2006).
[22] The AMA's Physician Masterfile contains data on more than one million physicians and residents, 82,000 medical students, and 353,737 graduates of foreign medical schools who reside in the United States.

company's products for patients matching a certain limited profile are identified as "niche subscribers." The data can also warn sales representatives that certain physicians are unfriendly to in-person sales calls, allowing the sales representative to design an alternative approach. As a Merck & Co. sales representative training guide explains, the data "pinpoints a prescriber's current habits" and helps the pharmaceutical company "identify which products are currently in favor with the physician in order to develop a strategy to change those prescriptions into Merck prescriptions."[23]

II. THE CONTROVERSY

Criticism of the marketing tactics of pharmaceutical companies dates to the 1950s, when Senator Estes Kefauver, then Chairman of the United States Senate's Antitrust and Monopoly Subcommittee, argued that pharmaceutical companies' promotional expenses were increasing drug costs.[24] Today, the debate over pharmaceutical company use of prescription data lays at the intersection of three broader and active national policy debates over (i) the cost of health care, including prescription drugs, (ii) the propriety of pharmaceutical company interaction with the medical profession, and (iii) patient privacy.[25] This section briefly offers an explanation and critique of each of these arguments.

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[23] Merck & Co., *Basic training participant guide*, (2002) available at http://dida.library.ucsf.edu/pdf/xib00a10.

[24] ESTES KEFAUVER, IN A FEW HANDS (Hamondsworth: Penguin 1965).

[25] Pew Prescription Project, *supra* note 7 (arguing that the use of PI data, (i) is "a key factor in the skyrocketing costs of prescription drugs and the increased usage of expensive brand-name medicines," (ii) "encourages the prescription of new drugs that might be riskier to patients than already established treatments," and (iii) "take[s] place without the consent, and generally without the knowledge, of physicians.").

1. Claim one: The use of PI data contributes to the high cost of prescription drugs.

It is estimated that in 2009 more than $297.5 billion was spent on prescription drugs in the United States.[26] According to the United States Government Accountability Office, prescription drug products accounted for an estimated 10.7% of health-care expenditures in the U.S. from 2000 to 2004.[27] Although this is a modest portion of all health-care expenditures, large percentage increases in the total expenditures on prescription drugs during the late 1990s and early 2000s, and large profit margins for drug companies caused alarm.[28] For example, from 2000 to 2001, total expenditures on prescription drugs grew by 18.1%.[29] This trend has moderated considerably, however, with total expenditures on prescription drugs increasing by merely 1.8% from 2007 to 2008, and by 4.5% from 2008 to 2009. In 2010, drug expenditures are expected to rise by a similar percentage from 2009 to 2010.[30]

The opponents of pharmaceutical company use of PI data argue that the data, and pharmaceutical detailing in general, increase prescription drug expenditures by enabling sales representatives to target physicians who commonly prescribe less costly generic drug products and convince them to prescribe more costly brand-

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[26] James M. Hoffman, Fred Doloresco, Lee C. Vermeulen, Nilay D. Shah, Linda Matusiak, Robert J. Hunkler, & Glen T. Schumock, *Projecting future drug expenditures*, 67 AMER. J. HEALTH-SYSTEM PHARM. 919, 921 (2010).

[27] United States Government Accountability Office, *Prescription drugs: Price trends for frequently used brand and generic drugs from 2000 through 2004* (2006).

[28] Kaiser Family Foundation, *Prescription Drug Costs: Background Brief*, available at http://www.kaiseredu.org/topics_im.asp?id=352&parentID=68&imID=1#_edn5b.

[29] Hoffman, *supra* note 27 at 921.

[30] *Id.*

name drugs[31] that are, according to critics, equally or less effective than the generic drugs.[32] As the Attorney General of New Hampshire argued before the United States District Court for the District of New Hamphsire, "[w]here equally effective and less costly generic medication is available," the PI data is used "to pressure physicians to change their prescriptions . . . and unnecessarily raise[] health care costs."[33]

HIOs and pharmaceutical companies respond to these criticisms by pointing to recent evidence suggesting that the era of rapid growth of prescription drug expenditures has passed as the "[i]ncreased availability and use of generic equivalents . . . continue[s] to moderate drug expenditure growth." [34] Additionally, proponents of PI data argue that it helps reduce, rather than increase prescription drug costs. First, the use of PI data reduces marketing costs as it allows pharmaceutical companies to spend less, not more, on marketing efforts and sampling because they are able to better focus their marketing efforts.[35] Secondly, studies suggest that promotional activities have played a critical role in decreasing the underuse of medications, leading to more effective treatment of illness and a

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[31] *Id. See also* Pew Prescription Project, *supra* note 7, and National Physicians Alliance, *Issue Brief: The Sale of Physician Prescribing Data Raises Health Care Costs-The National Physicians Alliance Calls For a Ban*, available at http://thehill.com/images/stories/whitepapers/pdf/IB_SalePhysData_Hirez.pdf.

[32] Pew Prescription Project, *supra* note 7.

[33] Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, IMS v. Ayotte, 2006 WL 4507569 (Sept. 1, 2006).

[34] Hoffman, *supra* note 27 at 926.

[35] Robert A. Musacchio & Robert J. Hunckler, *More Than a Game of Keep Away*, PHARM. EXEC. (May 1, 2006) available at http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=323311&pageID=4.

reduction in overall health-care costs.[36] Thirdly, PI data allows pharmaceutical companies to rapidly identify and educate physicians who may not be aware that more safe and effective treatments have become available.[37] Indeed, the health care profession is plagued with what is referred to as "clinical inertia," the failure of physicians to initiate needed therapies in a timely fashion.[38] Finally, without the highly-targeted, and thus rapid and cost-effective marketing efforts that PI data enables, some argue that the rate of adoption of newly-approved drugs would likely decrease—resulting in an increase in the costs of the drugs in order to recoup drug development costs over a shorter period of time.[39]

2. Claim two: Close pharmaceutical company interaction with the medical profession presents a conflict of interest that corrupts prescribing practices.

The criticisms of the use of PI data fit within the broader debate over the close relationship between the pharmaceutical industry and physicians.[40] Indeed, many are calling for far-reaching reforms to prevent conflicts of interests in the medical profession.[41] Often, the arguments against the use of PI data are not focused on PI

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[36] Julie M. Donohue, Marisa Cevasco, & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 N. ENG. J. MED. 673 (2007).
[37] Declaration of Thomas P. Wharton Jr., M.D., F.A.C.C in Support of Plaintiffs' Motion for Preliminary Injunction, IMS v. Ayotte, No. 06-CV-280-PB (July 20, 2006).
[38] Lawrence S. Phillips, William T. Branch, Curtiss B. Cook, Joyce P. Doyle, Imad M. El-Kebbi, Danial L. Gallina, Christopher D. Miller, David C. Zeimer, & Catherine S. Barnes, *Clinical Inertia*, 135 ANN. INTERN. MED. 825 (2001).
[39] Second Declaration of Peter Barton Hutt, IMS v. Sorrell, Nos. 1:07-cv-188, 1:07-cv-220. (May 29, 2008).
[40] *See* Thomas B. Stossel, *Regulating Academic-Industrial Research Relationships: Solving Problems of Stifling Progress?*, 353 N. ENGL. J. MED. 10 (2005) (arguing that "almost no publications" on the topic of physician conflicts of interest were published prior to 1987).
[41] *See e.g.*, Troyen A. Brennan, David J. Rothman, Linda Blank, David Blumenthal, Susan C. Chimonas, Janlori J. Cohen, Janlori Goldman, Jerome P. Kassirer, Harry Kimball, James Naughton, Neil Smelser, *Health industry practices that create conflict of interest. A policy proposal for academic medical centers*, 295 JAMA 429 (2006).

data, but rather on the practice of detailing more generally.[42] The use of PI data is not necessarily portrayed as a distinct harm, but merely a powerful tool in detailing.

Underlying the argument that the use of PI data unnecessarily results in increased drug expenditures is the presumption that such increased expenditures are not beneficial to public health.[43] Rather than representing justified additional expenditures, the prescription of more costly brand-name products is the result of a *distortion* or *corruption* of the physician's decision-making process. Indeed, to some, pharmaceutical gifting, sponsorship of Continuing Medical Education ("CME"), research grants, donations to medical schools, and complicity with professional organizations create conflicts of interest that at best undermine patient confidence in their physicians, and, at worst, present a serious public health problem.[44] Some evidence suggests that the public agrees, as surveys reveal that 74%-84% of patients are concerned over the effects of pharmaceutical gifting on their care.[45]

To many, sales representatives are highly-trained educators who provide critical information to physicians on their company's products in a convenient and efficient manner.[46] Indeed, given the increasing constraints on physician time, detailers provide an important service to physicians by digesting and delivering up-

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[42] *See e.g.*, Pew Prescription Project, *supra* note 7.
[43] *Supra* n. 33.
[44] *See e.g.*, Kassirer, *supra* n. 8. *See also* Pew Prescription Project, *supra* note 7 (claiming that "[m]arketing based on prescriber data often involves biased or inaccurate information about health risks, and encourages the prescription of new drugs that might be riskier to patients than already established treatments.").
[45] Ruben V. Gibbons, Frank J. Landry, Denise L. Blouch, David L. Hones, Frederick K. Williams, Catherine R. Lucey, & Kurt Kroenke, *A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts*, 13 J. GEN. INTERN. MED. 151 (1998).
[46] Richard Levy, *The role and value of pharmaceutical marketing*, 3 ARCH FAM MED 327 (1994).

to-date scientific research that has implications on the physician's everyday practice. For example, one study found that 75% of the physicians surveyed considered the information provided by sales representatives to be "very useful" (15%) or "somewhat useful" (59%).[47]

Critics, however, portray sales representatives as young, attractive, "reps in cars" handing out free meals and samples and employing messaging tactics deliberately designed to "manipulate" physicians into prescribing their products.[48] These criticisms are fueled by rare, yet disturbing, evidence that some sales representatives view their interactions with physicians as a *quid-pro-quo* relationship, or believe they have the ability to manipulate physicians into prescribing their products.[49] Many argue that even in the absence of *quid-pro-quo* relationships, pharmaceutical gifting leads physicians to subconsciously increase the number of prescriptions they write for the giver's drug product.[50] Critics counter the "educational" function of sales representatives by pointing out that the

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[47] Kaiser Family Foundation, *National survey of physicians*, (2006) available at http://www.kff.org/rxdrugs/upload/3057-05.pdf .

[48] A. Fugh-Berman, S. Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLOS MED 150 (2007), available at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040150#pmed-0040150-b026.

[49] *See e.g.*, Gariner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucratice Insulin Market Are Under Scrutiny*, N.Y. Times (Jan. 28, 2006) available at http://www.nytimes.com/2006/01/28/national/28insulin.html?pagewanted=print (quoting an e-mail from a district manager of Novo Nordisk stating that "[o]ur goal is 50 or more scripts per week for each territory ... If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!").

[50] Fugh-Berman, *supra* note 49.

accuracy of the information they provide is questionable.[51] As a former editor of the New England Journal of Medicine stated, "[t]o rely on drug companies for unbiased evaluations of their products makes about as much sense as relying on beer companies to teach us about alcoholism." [52]

Despite the frequency with which criticisms of detailing are asserted, the exact effect of detailing on the prescribing practices of physicians is the subject of much debate and dramatically varying results. For example, one study found that detailing resulted in a dramatic increase in the number of prescriptions for particular antidepressants—from 10% to 89% of all medications prescribed for newly-admitted patients—during the period of time in which the sales representative was making frequent visits.[53] Another study demonstrated that physicians who accept travel to pharmaceutical company sponsored symposia at resort locations were two to three times more likely to prescribe the company's drugs after they returned.[54] Additionally, social science studies focus on the effects of giving gifts of even marginal monetary value, arguing that they can create a subconscious willingness of the receiver to reciprocate.[55] Interestingly, 84% of

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[51] Michael G. Ziegler, Pauline Lew, & Brian C. Singer, *The accuracy of drug information from pharmaceutical sales representatives*, 273 JAMA 1296 (1995).
[52] Marcia Angell, *The pharmaceutical industry—to whom is it accountable?*, 342 N ENGL. J. MED. 1902 (2000).
[53] Thomas L. Schwartz, Daniel J. Kuhles, Michael Wade, & Prakash S. Masand, *Newly admitted psychiatric patient prescriptions and pharmaceutical sales visits,* 13 ANN CLIN. PSYCH'Y 159 (2001).
[54] Kassirer, *supra* n. 8 (citing James P. Orlowski & Leon Wateska, *The effects of pharmaceutical firm enticements on physician prescribing patters: There's no such thing as a free lunch*, 103 CHEST 270 (1992)).
[55] Dana Katz, Arthur L. Caplan, & Jon F. Merz, *All gifts are large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving*, 3 AM. J. BIOETH. 39 (2003). *See also* Ashley Wazana, *Physicians and the pharmaceutical industry: is a gift ever just a gift?*, 283 JAMA 373 (2000); and Brooks King-Casas, Damon Tomlin, Cedric Anen, Colin F. Camerer, Steven R.

medical students believe that detailing influences other physicians' prescribing behavior, yet only 39% believed that it had the potential to influence their own prescribing determinations.[56] Even some practicing physicians admit that free meals and gifts do influence their prescribing habits in marginal situations where the doctor believes that competing drugs are equivalent.[57]

Nevertheless, the exact effect of pharmaceutical detailing on prescribing habits remains difficult to quantify.[58] Some have concluded that physicians are not easily persuaded by sales representatives.[59] Importantly, even many of the studies that do suggest detailing increases prescriptions nevertheless agree that whether or not these prescriptions are beneficial to patient health is an open question.[60]

3. Claim three: The use of PI data is a threat to patient and physician privacy. Opponents of the use of PI data claim that the data is sold without the consent and knowledge of physicians,[61] and that its use in detailing amounts to an intrusion into

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Quartz, & P. Read Montague, *Getting to know you: Reputation and trust in a two-person economic exchange*, 308 SCIENCE 78 (2005).

[56] Michael A. Steinman, Michael G. Shilpak, & Stephen J. McPhee, *Of principles and pens: Attitudes and practices of medicine housestaff toward pharmaceutical industry promotions*, 110 AMER. J. MED. 551 (2001).

[57] Kassirer, *supra* n. 8 at 11 (citing Adams, C. *Doctors 'Dine 'n' Dash in style, as drug firms pick up the tab*, Wall St. J. (May 14, 2001 at 1).

[58] Congressional Budget Office, *supra* n. 3 (noting that "some analyses have found positive effects on the number of prescriptions written for the targeted drug, but others suggest that detailing's effects are unclear."). *See also* Puneet Manchanda & Elisabeth Honka, *The effects and role of direct-to-physician marketing in the pharmaceutical industry: an integrative review*, 5 YALE J. HEALTH POLICY LAW AND ETHICS 785, 795 (2005) (noting that while the effect of detailing on prescribing behavior is statistically significant, yet there is little consensus about the size of the effect).

[59] Srindhar Narayanan, Puneet Manchada, & Pradeep K. Chintagunta, *Temporal Differences in the Role of Marketing Communication in New Product Categories*, J. MARKET. RES. 278 (August 2005).

[60] *See* Wazana, *supra* note 56 at 378 (noting that some studies found that detailing resulted in "improved ability to identify the treatment for complicated illnesses," yet cautioning that "[n]o study used patient outcome measures.").

[61] Pew Prescription Project, *supra* note 7.

the physician-patient relationship.[62] Many patients and physicians share these concerns. For example, in 2009, the Vermont Medical Society unanimously passed a resolution stating that the use of PI data "is an intrusion into the way physicians practice medicine"[63] and more than 70% of Americans express concerns over the privacy of their medical information.[64] While PI data, as explained above, is "de-identified" prior to being transmitted to HIOs, opponents also argue that de-identified PI data can often be "re-identified" by matching the de-identified data with other commercial or publicly-available databases,[65] raising the specter of discrimination based on medical condition.[66] In fact, a pharmaceutical industry publication asserts that ""the growth and networking of computerized databases has made it possible to identify the 'de-identified' people with surprising accuracy. Thus, your anonymity isn't guaranteed even if a database doesn't contain information that easily identifies you."[67]

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[62] Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, IMS v. Ayotte, No. 06-CV-280-PB (Sept. 1, 2006) (claiming that the use of prescriber-identifiable prescription data by pharmaceutical companies to pressure physicians to change their prescriptions intrudes on the prescribing practices of New Hampshire's physicians and unnecessarily raises health care costs.).

[63] Brief of Amicus Curiae Electronic Privacy Information Center (EPIC) In Support of Appellee and Urging Affirmance, IMS v. Sorrell, No. 09-1913-cv (L) (citing Vt. Stat. Ann. tit. 33, § 1998(20) (2009)).

[64] Harris Interactive, *The Benefits of Electronic Medical Records Sound Good, but Privacy Could Become a Difficult Issue*, (Feb. 8, 2007) available at http://www.harrisinteractive.com/NEWS/allnewsbydate.asp?NewsID=1174.

[65] *Supra* n. 63 at 9 (citing Khaled El Emam, Sam Jabbouri, Scott Sams, Youenn Drouet, & Michael Power, *Evaluating Common De-identification Heuristics for Personal Health Information*, 8 J. MED. INTERNET RES. 4 (2006))

[66] Catherine A. Martin & Tamara R. Tenney, *Preparing for quality-based payments: trends and legal barriers to successful implementation*, 2 J. HEALTH & LIFE SCIENCES LAW 1 (2009).

[67] Jennifer L. Klocke, *Prescription records for sale: privacy and free speech issues arising from the sale of de-identified medical data*, 44 Id. L. Rev. 511 (2008) (citing Herb Edelstein & Janet Millenson, *Data Mining in Depth: Data Mining and Privacy*, 65 DM REV. (Dec. 2003), *available at* http:// www.dmreview.com/issues/20031201/7768-1.html.).

Proponents of the use of PI data counter these privacy concerns by pointing to the benefits that the use of PI data enables, as increased transparency results in better health outcomes and improved patient safety.[68] For example, the gathering of PI data for commercial purposes enables a host of non-commercial uses for government and academia. Additionally, the PI data allows pharmaceutical companies to quickly identify physicians who need to be contacted in the event of a newly-discovered side effect or recall. The AMA has urged HIOs to use PI data to provide health care providers with important information about their own practices, including comparisons of physician prescribing patterns among peers, patient compliance with treatment, and to assist in the development of patient-outcome-based compensation schemes, disease management programs, and public health monitoring.[69] In short, the profit made from the sale of PI data to pharmaceutical companies enables many other beneficial applications. As one industry publication claimed "[t]he industry underwrites the substantial costs that HIOs incur when collecting and processing the information. Without this support, the data would not exist."[70]

III. THE REGULATORY RESPONSE

Four states—New Hampshire, Maine, Massachusetts, and Vermont—have enacted laws banning the sale, use, or license of PI data for commercial purposes or

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[68] Kevin O'Reilly, *Prescription Data Opt-Out Law Upheld in Maine*, Nat. Legislative Action on Prescription Drug Prices, available at http://www.reducedrugprices.org/read.asp?news=5918.
[69] American Medical Association, Reports of Board of Trustees, (December 2004) available at http://www.ama-assn.org/meetings/public/interim04/bot_reports.pdf
[70] Musacchio, *supra* n. 35.

conditioning the use of such data on compliance with certain regulations. Several additional states have considered, or are considering, similar legislation.[71] On the federal level, in 2009, the U.S. House of Representatives rejected an outright ban on data-mining, but opted to study the issue, and the U.S. Senate rejected an amendment offered by Senators Herb Kohl (D-WI) and Dick Durbin (D-IL) that would have banned the commercial use of PI data.[72]

In June 2006, New Hampshire became the first state in the nation to prohibit the use of PI data for marketing purposes. The Prescription Information Confidentiality Act ("PICA"),[73] provides for both criminal and civil penalties for pharmacies, insurance companies, and similar entities who license, transfer, or sell PI data "for any commercial purpose."[74] Vermont and Maine followed closely behind New Hampshire, enacting similar legislation in 2007. Vermont passed the Prescription Confidentiality Law, which bans the use of a physician's PI data for commercial purposes unless the physician *opts-in* to allowing pharmaceutical companies to access his or her data. The Vermont legislation also requires

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[71] These include Arizona (Ariz. Rev. Stat. Ann. § 32-1973 (2009), District of Columbia (D.C. Code § 3-1207.41 (2008) (http://www.asi-solutions.com/files/DC_SafeRx_Bill.pdf), Illinois (H.B 1459, 95th Gen. Assem. (Ill. 2007)), Kansas (S.B. 229 (Kan. 2007)), Maine (Me. Rev. Stat. Ann. tit. 22, § 1711-E (2005)), Maryland (S.B. 266 (Md. 2007)), Massachusetts (S.B. 1275 (Mass. 2007)), Nevada, (S.B. 231 (Nev. 2007)), New Hampshire (N.H. Rev. Stat. Ann. §§ 318:47-f, 318-47g, 318-B:12 (2006)), New York, (H.B. 5891B, Reg. Sess. (N.Y. 2009)), North Carolina (S.B. 159, Gen. Assem. (N.C. 2007)), Rhode Island (S.B. 2683, Gen. Assem. (R.I. 2008)), Texas (S.B. 1620 (Tex. 2007)), Vermont (Vt. Stat. Ann. Tit. 18, § 4631 (2009), Washington (H.B. 1850 (Wash. 2008)), and West Virginia (W. Va. Code. § 30-5-12c (2008)).

[72] Ed Silverman, *Senate Amendment Would Block Data Mining*, PHARMALOT (Dec. 10, 2009) available at http://www.pharmalot.com/2009/12/senate-amendment-would-block-data-mining/.

[73] 2006 N.H. Laws § 328, codified at N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12 (IV) (2006).

[74] The statute defines "commercial purpose" as including, but not limited to, "advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or elevate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force."

physicians to disclose to patients the range of possible drug treatments, as well as the costs, benefits and risks of each treatment, and creates a consumer fraud cause of action for violations of the statute.[75] Maine similarly enacted legislation prohibiting the use of PI data "for any marketing purpose," but it requires Maine physicians to *opt-out* of allowing pharmaceutical companies to access their data.[76] Finally and most recently, on July 1, 2009, Massachusetts promulgated regulations requiring manufacturers to (i) offer physicians the ability to *opt-out* of allowing their PI data to be used for marketing purposes, (ii) respect the confidentiality of the data by training employees on data handling and establishing disciplinary actions for data misuse, and (iii) designate an "internal contact person to handle inquiries regarding the use of the data."[77]

The AMA has also responded to the criticisms of the use of PI data in detailing. In 2001, the AMA issued guidelines for the use of PI data by pharmaceutical companies.[78] However, the guidelines were unsuccessful in assuaging physician concerns and growing scrutiny by state legislatures,[79] and on July 1, 2006, the AMA created the Prescribing Data Restriction Program ("PDRP"), which provides physicians with the ability to restrict their PR data from being used by pharmaceutical company employees who have direct contact with physicians.[80]

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[75] VT. STAT. tit. 18, §§ 4631, 4622; tit. 33 § 2004; tit. 9 § 2466a (2007).
[76] ME. REV. STAT. tit. 22, § 1711-E (2007).
[77] 105 MASS. CODE REGS. 970.005(2) (2009).
[78] American Medical Association, *Best Practice Guidelines for Use of Prescribing Data by Industry*, (2001).
[79] Musacchio, *supra* n. 35.
[80] While the PDRP restricts pharmaceutical sales representatives from accessing PR data on a physician enrolled in the PDRP, the pharmaceutical company's headquarters may still use such information in designing its marketing or compensation practices.

The PDRP is designed to serve as an alternative to more restrictive state legislation,[81] which if adopted more broadly, could threaten the reported $47.5 million in annual revenue the AMA generates from licensing the Physician Masterfile and similar databases.[82] While the PDRP has not prevented all state legislation, more than 26,000 physicians have enrolled in the program, and a survey of physicians revealed that 96% of physicians were either "very satisfied" or "satisfied" with the PDRP.[83] Referencing the PDRP has also been a powerful tactic in lobbying against state legislation restricting the use of PI data.[84]

IV. LEGAL CHALLENGES

The New Hampshire, Maine, and Vermont statutes were immediately challenged as violations of HIO companies' First Amendment rights. In July 2006, IMS Health Inc. and Verispan, LLC filed a complaint with the United States District Court for the District of New Hampshire seeking declaratory and injunctive relief from the statute. On April 30, 2007, the New Hampshire District Court ruled in their favor, finding that the statute restricted "commercial speech" protected by the First Amendment, and was thus subject to intermediate scrutiny under the test established by the Supreme Court of the United States in *Central Hudson Gas & Elec. Corp. v. Pub Serv. Comm'n*, 447 U.S. 557 (1980). Under *Central Hudson*, "commercial speech" that concerns lawful activity and is truthful and not

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[81] Musacchio, *supra* n. 35.
[82] American Medical Association, *Annual Report 2009,* (2009) available at http://www.ama-assn.org/ama1/pub/upload/mm/37/2009-annual-report.pdf.
[83] O'Rielly, *supra* n. 68.
[84] IMS Health Inc. v. Ayotte, 490 F. Supp 2d 163, 173 (D.N.H. 2007) (noting that IMS Health and Verispan argued that the PDRP was adequate in testifying before the New Hampshire legislature).

misleading may only be restricted if, (i) if there is a substantial government interest in prohibiting the speech, (ii) if the restriction "directly advances" the substantial government interest, and (iii) if the restriction is no more extensive than necessary.[85]

The New Hampshire Attorney General argued that the state had two interests in restricting the commercial use of PI data: (1) "limiting unwarranted intrusions into the decision-making process of prescribing physicians,"[86] and (2) "prevent[ing] pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs."[87] According to the District Court, the New Hampshire statute failed to promote either of these interests because the law did not involve "solicitations that invade the tranquility of the home or that target vulnerable victims," and the state "failed to prove that any reductions in health care costs that may result [from the ban on commercial use of PI data] can be achieved without compromising patient care."[88] The district court also found the law to be broader than necessary, as it prohibited potentially beneficial targeting efforts that the use of PI data enables, and unnecessary, as the state could instead ban industry gifts to physicians, further educate physicians about generic drug products, or utilize the state's Medicaid Pharmacy Program to

[85] 446 U.S. at 566.
[86] IMS v. Ayotte, 490 F. Supp. 2d at 179.
[87] *Id.* at 180.
[88] *Id.* at 181.

require prior authorization before a physician could prescribe a name-brand drug whose cost-effectiveness was questionable.[89]

In November 2008, the United States Court of Appeals for the First Circuit reversed the District Court, finding that the New Hampshire law "principally regulate[d] conduct, and to the extent that the challenged portions impinge[d] at all upon speech, that speech is of scant societal value."[90] In the alternative, the First Circuit held that even if PI data were considered to be commercial speech, the requirements of the *Central Hudson* test had been met. The Circuit noted that while "the state 'must demonstrate that the harms it recites are real and that the restriction will in fact alleviate them to a material degree," certitude was not required.[91] The Circuit accepted the New Hampshire legislature's claims about the effects of sales representative use of PI data on physician prescribing habits, describing PI data as "a tool for tipping the balance of bargaining power in their [sales representatives'] favor" and accepting the legislature's determination that it increased health care costs and "compromised the integrity of physician decision-making."[92] IMS Health Care Inc. and Verispan petitioned the Supreme Court for a writ of certiorari, but on June 29, 2009, the Supreme Court denied their request.

The First Circuit's decision in *IMS v. Ayotte* is a landmark ruling in the field of data-mining. In August 2010, the First Circuit, in *IMS Health Inc. v. Mills*, 2010

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[89] *Id.* at 182 (citing 2004 N.H. Laws, ch. 188).
[90] IMS v. Ayotte, 550 F.3d 42, 52 (1st Cir. 2008) *cert. denied*, 129 S. Ct. 2864 (2009) (further explaining that "[t]he plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.").
[91] *Id.* at 55.
[92] *Id.* at 54.

WL 3025496 (1st Cir. Aug. 4, 2010) reiterated its holding in *Ayotte* by overruling a decision of the United States District Court for the district of Maine which held that Maine's restrictions on the use of PI data were unconstitutional under the First Amendment.[93] Soon after the Supreme Court denied certiorari in *Ayotte*, the Vermont federal district court upheld Vermont's Prescription Confidentiality Law in *IMS v. Sorrell*, agreeing with the First Circuit that the law satisfied the *Central Hudson* intermediate-scrutiny test.[94] This case is currently on appeal to the Second Circuit Court of Appeals, and as of August 31, 2010, a decision is expected to be announced any day.

V. THE IMPACT OF *CITIZENS UNITED v. FEC*

The Supreme Court likely denied certiorari in *IMS v. Ayotte* because the decision represented the first circuit court ruling on the constitutionality of restrictions on commercial use of PI data. Indeed, at the time the petition for writ of certiorari from the First Circuit was submitted, no other circuit court had weighed in on the issue. The challenge to Vermont's Prescription Confidentiality Law, however, which is currently pending before the Second Circuit, may present just such a case.[95] If the Second Circuit strikes down the Vermont Prescription Confidentiality Law, a circuit split will result, rendering a grant of certiorari from the Supreme Court much more likely. Even if the Second Circuit upholds the Vermont law, the number of states considering similar legislation, and the commitment of HIOs to

[93] IMS Health Inc. v. Rowe, 532 F. Supp. 2d 183 (D. Me. 2008).
[94] IMS v. Sorrell, 631 F. Supp. 2d 429 (D.Vt. 2009).
[95] While the Second Circuit heard oral arguments in IMS v. Sorrell in October 2009, as of the writing of this article, a decision from the Second Circuit has yet to be announced.

challenging such laws, is likely to result in a divergence among the circuits and an eventual Supreme Court ruling.

The purpose of this section is to predict how the current Supreme Court is likely to rule on the constitutionality of state legislation restricting the use of PI data for commercial purposes. To do so, a brief analysis of the Supreme Court's commercial speech jurisprudence is first conducted. Next, the section argues that a seemingly unrelated 2010 Supreme Court case involving federal campaign finance laws, *Citizens United v. FEC*, is likely to have important implications for how the current Court is likely to view the regulation of PI data.[96]

1. The Supreme Court's evolving commercial speech jurisprudence.

Prior to the Supreme Court's seminal ruling in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), commercial speech was treated as wholly beyond the protection of the First Amendment. For example, in *Valentine v. Christensen*, 316 U.S. 52 (1942), the Court held that handbills advertising submarine tours on one side, and listing grievances with local government on the other, were entitled to no First Amendment protection. Following *Virginia Pharmacy*, commercial speech received an intermediate level of First Amendment protection. The case did not resolve the issue permanently, however, as many believe that no other area of First Amendment jurisprudence has proved so divisive.[97]

[96] 558 U.S. 50 (2010).
[97] Robert C. Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. Rev. 1 (2000).

In resolving a question regarding the constitutionality of a restriction on commercial speech, one must first determine whether the speech at issue is properly categorized as "commercial speech." The Supreme Court first elaborated on the standard for this determination in *Bigelow v. Virginia*, 421 U.S. 809 (1975), stating that "[t]he diverse motives, means, and messages of advertising may make speech 'commercial' in widely varying degrees."[98] And the following year, in *Virginia Pharmacy*, the court defined commercial speech as speech that "does no more than propose a commercial transaction."[99] Yet, only three years later, in *Bolger v. Youngs Drug Products Corp.,* 463 U.S. 60 (1983), the Court was confronted with the question of whether informational pamphlets accompanying contraceptives were commercial speech. The Court held that the combined factors of (i) the promotional nature of the pamphlets, (ii) reference to specific products, and (iii) the manufacturer's economic motivation for sending the pamphlets, rendered them commercial speech.[100] The relative importance of each of these factors is unclear, and the modern standard is often rephrased as inquiring as to whether the communication is "strictly business."[101]

Once speech is categorized as commercial, the current standard the Supreme Court utilizes for analyzing restrictions on commercial speech is the intermediate-scrutiny test elaborated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 and explained above. But, the Supreme Court has

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[98] 421 U.S. at *826.*
[99] 425 U.S. 748 at 761.
[100] 463 U.S. at 67.
[101] Friedman v. Rogers, 440 U.S. 1, 11 (1979).

applied the *Central Hudson* test inconsistently, and the current trend appears to be in favor of increased scrutiny—some argue strict scrutiny—of restrictions on commercial speech.[102]

This increased scrutiny has taken the form of (i) requiring more convincing evidence that the government's substantial interest is advanced by the restrictions on speech, and (ii) a more thorough analysis of less restrictive alternatives.[103] For example, in *44 Liquormart Inc. v. Rhode Island*, a unanimous Court overturned Rhode Island laws banning liquor price advertisements prior to the point of sale, finding that despite the reasonable assumption that prohibiting price advertising will result in less open competition, leading to higher prices and hence lower demand, "the State has presented no evidence to suggest that its speech prohibition will *significantly* reduce marketwide consumption."[104] More recently, the Supreme Court's decision in *Thompson v. Western States Medical Center* represents a strict application of the *Central Hudson* requirement that restrictions on speech be no more extensive than necessary.[105]

2. The impact of Citizens United v. FEC.

The Supreme Court's 2010 decision in *Citizens United v. Federal Election Commission*, invalidating the Bipartisan Campaign Reform Act's prohibition of corporate independent expenditures, has important implications for the Supreme

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[102] Post *supra* note 98. *See also* Tamara R. Piety, *Commentary, Citizens United and the Threat to the Regulatory State*, 109 Mich. L. Rev. 16 (2010).
[103] *See* Adam Larson, *Commercial Speech & Prescription Drug Promotion: Where have we been & where are we going*, Food and Drug Law: An Electronic Book of Student Papers (2005), available at http://leda.law.harvard.edu/leda/data/704/Larson05.html#fnB251.
[104] 517 U.S. 484, 505 (1996) (emphasis in original).
[105] 535 U.S. 357 (2002) (stating that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.").

Court's commercial speech jurisprudence, and important implications for the anti-distortion rationale utilized by the First Circuit in upholding restrictions on the use of PI data for commercial purposes.[106]

a. *Citizens United* further develops the Supreme Court's trend towards increased scrutiny of restrictions on commercial speech.

Citizens United conflicts in two important ways with the treatment of commercial speech as less valued speech subject to intermediate, as opposed to strict, scrutiny. First, in *Citizens United* the Court repeatedly identified corporations as "citizens," emphasizing the unconstitutionality of focusing on the *identity* of a speaker.[107] Second, if one cannot distinguish between corporate and non-corporate "citizens" in regulating speech, then the argument can be made that because commercial speech is central to the existence of a corporate "citizen," then the same standard of review should apply to state regulation of commercial speech as to an individual's speech.[108] To do otherwise would be to unavoidably discriminate based on the identity of the speaker. Indeed, some have argued that *Citizens United* "suggests that with the proper case, there is an increased likelihood the Supreme Court will either do away with the commercial speech doctrine . . . or retain the doctrine but apply strict scrutiny review.[109]

b. *Citizens United* reflects an unwillingness of the Court to accept the distortion or corruption rational which underlies the restrictions on the use of PI data for commercial purposes.

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[106] 558 U.S. 50, 130 S.Ct. 876 (2010).
[107] *Id.* at 913.
[108] Brief of Washington Legal Foundation and National Association of Manufacturers as Amici Curiae in Support of Petitioners, Philip Morris USA, Inc. v. United States, Nos. 09-976, 09-977, 09-1012 (Mar. 22, 2010).
[109] Tamara R. Piety, *Commentary, Citizens United and the Threat to the Regulatory State*, 109 Mich. L. Rev. 16 (2010).

While the implications of *Citizens United* on the commercial speech doctrine are important, the Supreme Court need not abolish or modify its existing commercial speech doctrine in order to strike down restrictions on the commercial use of PI data. In fact, increased scrutiny by the Court is likely to come within the existing *Cental Hudson* framework by (i) requiring a stronger showing that the restrictions on commercial speech directly advance the substantial interest of the states, and (ii) conducting a closer examination of the potential alternative methods of advancing that interest. As explained above, essential to the arguments in favor of restricting the commercial use of PI data is the contention that the data "tip[s] the balance of bargaining power" in favor of sales representatives, allowing them to "manipulate" or "compromise[] the integrity of physician decisionmaking."[110] This same rationale, albeit in a different context, was emphatically rejected by the Court in *Citizens United*.

Central to the Court's ruling in *Citizens United* was a discussion of the long-recognized compelling government interest in preventing "corruption or the appearance of corruption" in the electoral context.[111] Prior to the ruling, the Supreme Court had repeatedly held that the compelling governmental interest of preventing "corruption or the appearance of corruption" justified a broad range of limitations on the election-related activities of individuals, corporations, labor unions, political parties, and political action committees.[112] The Court also defined

[110] 550 F.3d at 54.
[111] Buckley v. Valeo, 424 U.S. 1 (1976).
[112] *Id.*

this interest broadly, encompassing "the avoidance of the appearance of improper influence,"[113] and, in 2003 in *McConnell v. FEC,*[114] further explained that the court had "firmly established that Congress' legitimate interest extends beyond [quid-pro-quo] corruption to curbing 'undue influence on an officeholder's judgment, and the appearance of such influence.'"[115]

Citizens United represents a significant narrowing of this anti-corruption rationale. Justice Kennedy's majority opinion stated plainly that "we now conclude that independent expenditures, including those made by corporations, do not give rise to corruption of the appearance of corruption."[116] Justice Kennedy continued, asserting that "[t]he fact that speakers may have influence over or access to elected officials does not mean that these officials are corrupt."[117] The narrowing of the anti-corruption interest in the political speech context has important implications for state restrictions on the use of PI data. In *Citizens United*, the Court clarified that it is unlikely to view such a rationale favorably, and unlikely to defer to legislative judgments regarding such undue influence or favoritism. [118]

Admittedly, *Citizens United* is a political, rather than commercial, speech case. Nonetheless, the underlying rationale is similar—preventing the distortion of judgment alleged to result from undue influence. The Supreme Court is even more

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[113] *Id. at 27.*
[114] 540 U.S. 93 (2003).
[115] *Id.* at 143 (citing Federal Election Comm'n v. Colorado Republican Federal Campaign Comm., 533 U.S. 431, 441).
[116] 130 S. Ct. at 909.
[117] *Id.*
[118] *Id.* (stating that "[r]elaince on a 'generic favoritism or influence theory . . . is at odds with standard First Amendment analyses because it is unbounded and susceptible to no limiting principle.'").

likely to view this rationale skeptically when the information being provided is truthful. Courts have consistently overturned restrictions on commercial speech when those restrictions are motivated by "a fear that people would make bad decisions if given truthful information."[119] As one expert observed, this Court opposition to "paternalism" means that "[s]tate efforts to advance legitimate interests through the suppression of accurate information [are likely to] arouse[] the suspicion of an increasing number of justices."[120]

Restrictions on the commercial use of PI data are a prime target for such suspicion from the Court as they represent (i) an attempt to limit, or at least to make less effective, the transfer of truthful information to physicians, and (ii) are motivated by a concern that such information and the relationships cultivated through the transfer of such information result in undue influence on physicians judgment. Thus, the Court is likely to agree with the New Hampshire district court, when it reasoned that "[h]ealth care providers are highly trained professionals who . . . are more able than the general public to evaluate truthful pharmaceutical marketing messages" and concluded that "the State simply does not have a substantial interest in shielding them from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information."[121]

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[119] Thompson v. Western States Medical Center, 535 U.S. 357 (2002) (citing Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976)). *See also* Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51, 70 (D.D.C.1998) (stating that "the Supreme Court has repeatedly rejected governmental attempts to equate less information with better decision-making" and that "[t]o endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection . . . is practically an engraved invitation to have the restriction struck.")

[120] *See* Post, *supra* note 98.

[121] 490 F. Supp. 2d at 181.

VI. CONCLUSION

It is likely only a matter of time before the Supreme Court considers the constitutionality of restricting the use of PI data for commercial purposes. Necessary to the rationale supporting restrictions on the commercial use of PI data is the claim that it facilitates the manipulation, and hence, corruption, of physicians' decision-making process with regard to prescribing medication. After *Citizens United*, however, the Supreme Court is likely to subject restrictions on commercial speech to increased scrutiny, and is unlikely to view such the anti-corruption rationale favorably. Thus, the Supreme Court is likely to rule that restrictions on the use of PI data for commercial purpose are unconstitutional under the First Amendment.